UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,861	09/05/2003	Yi Wang	ALXN-PO1-102	7250

28120 7590 10/25/2010

ROPES & GRAY LLP
IPRM - Floor 43
PRUDENTIAL TOWER
800 BOYLSTON STREET
BOSTON, MA 02199-3600

EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
10/25/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/655,861	WANG, YI	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,20,21 and 45-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18,20,21 and 45-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/16/2010, 01/14/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission, filed on 12/08/2008, has been entered.

2. Applicant's Response to Notice of Non-Compliant Amendment, (37 C.F.R. § 1.121), filed 08/12/2010, is acknowledged.

3. Applicant's amendment, filed 08/12/2010, has been entered.
Claims 1-9 have been amended.
Claims 51-58 have been added.
Claims 19 and 22-44 have been canceled.

Claims 1-18, 20-21 and 45-58 are pending.

4. Applicant's election without traverse of Group I, drawn to methods of treating asthma with anti-C5 antibodies, filed 11/13/2006, has been acknowledged (e.g., see Office Action, mailed 03/13/2007).

Therefore, the "compound" of the newly added claims 51-58 is anti-C5 antibodies as it reads on the originally elected invention.

It is noted that the "suitable compounds for combination therapy" recited in claims 20 and 51 (e.g., "steroids, β2 adreno receptor agonists, PDE inhibitors, CD23 antagonists, IL-13 antagonists, cytokine release inhibitors, histamine H1 receptor antagonists, anti-histamines and histamine release inhibitors") have been subject to prosecution in the instant application.

5. Applicant's arguments, filed 08/12/2010, have been fully considered but rendered moot in view of the New Grounds of Rejection set forth herein.

6. Priority.

The effective filing date of the instant claims 1-2 is deemed to be the filing date of instant priority application USSN 60/408,571, filed 09/06/2002.

With respect to certain claim limitations, the following is noted.

The previous priority applications do not support sufficient written description for the instant claims, including limitations such as "reducing the severity of an asthma attack" (e.g., see claim 3), "reducing airway obstruction in a subject" (e.g., see claim 4), "increasing air flow in a subject" (e.g., see claim 5), "reducing bronchial spasms in a subject" (e.g., see claim 6), "treating a chronic obstructive pulmonary disease" (e.g., see claim 7), "having established airway inflammation" (e.g., see claim 8) and "effective bronchial-dilating amount of an anti-C5 antibody" (e.g., see claim 9), "nebulization" (e.g., see claims 45-50), "combination therapy with all of members recited in claims 20 and 51", "without substantially reducing systemic complement activity in a subject" (e.g., see claim 21) and bind / block the generation of / block the activity of one or more complement components (e.g., see claims 55-58) and "compounds which block the engagement of complement component receptors" (e.g., see claims 55-58).

Applicant should compare the priority applications with the instant claims for differences in the description of the claimed methods of treatment with anti-C5 antibodies.

For example, USSNs 60/469,189 and 60/408,571 appear to be more limited in describing the treatment with anti-C5 antibodies in a subject when compared to the instant claims.

Therefore, claims 3-18, 20-21 and 45-58 are deemed to have an effective filing date of the instant application USSN 10/655,861, filed 09/05/2003.

If applicant desires priority prior to 09/05/2003, applicant is invited to point out and provide documentary support for the priority of the instant claims.

Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

Obviousness is not the standard for the addition new limitations to the disclosure as filed. It is noted that entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977).

A claim as a whole has only one effective filing date.
See Studiengelsellschaft Kahle m.b.H. v. Shell Oil Co. 42 USPQ2d 1674, 1677 (Fed. Cir 1997).

7. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected. Appropriate corrections are required.

Trademarks should be capitalized or accompanied by the ® or ™ symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP 608.01.
For example, see page 6, line 18 of the specification.

Applicant is required to make all appropriate rejections.

8. Claim Objections.

Claims 20, 51 are objected to because "IL-13" (and not "IL 13") is the proper designation of this cytokine.

9. Claims 15 and 55-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 15 is indefinite in the recitation of "functional fragment thereof" because their characteristics are ill-defined and not distinctly claimed. Although it appears that applicant intends for the "functional fragments thereof" to be limited to C5-specific antigen binding fragments, it is noted that the Fc component of antibodies / immunoglobulins comprise a number of antibody- / immunoglobulin-related functions, which are distinct from the antigen specificity associated with the claimed invention.

With respect to "functional fragments", applicant is invited to amend the claims to recite "CD40-binding fragments" to clarify applicant's intent of the appropriate specific antigen binding fragments of the claimed invention, if supported by the specification as-filed.

B) Claims 55-58 are indefinite in the recitation of "compounds which bind / block the generation of / block the activity of one or more complement components" and "compounds which block the engagement of complement component receptors" because it is unclear whether the functions read on *a single compound* with multiple targets or whether the functions read on *multiple compounds* or *both*.

C) Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06

10. The following is a quotation of the first paragraph of 35 U.S.C. § 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claim 15.

It is apparent that the h5G1.1 antibody is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of a pertinent cell line / hybridoma which produces this antibody. See 37 CFR 1.801-1.809.

Given the disclosure and the claims (e.g. see claims 21-22) encompassing the instant h5G1.1 antibody set forth in U.S. Patent No. 6,355,245 (e.g., see pages 14-15, overlapping paragraph of the specification);
the conditions for the deposit of biological materials under 35 USC 112, first paragraph, with respect to h5G1.1 have been satisfied.

12. Claims 2, 11-18, 51 and 57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

The instant claims are drawn to "preventing asthma attacks".

In vitro and animal model studies have not correlated well with in vivo clinical trial results in patients. Since the therapeutic indices of immunosuppressive drugs or biopharmaceutical drugs can be species- and model-dependent, it is not clear that reliance on the in vitro and in vivo experimental observations as well as the clinical experience with treating various pulmonary conditions, including asthma with anti-C5 antibodies accurately reflects the relative ability or efficacy of the claimed methods to prevent asthma attacks with anti-C5 antibodies.

For example, pages 4-5 of the specification describes the following.

Currently, the treatments for asthma are not always adequate and many have serious side effects. The general goals of drug therapy for asthma are prevention of bronchospasm and control of airway hyperreactivity or hyperresponsiveness, an indication of airway inflammation. It is very difficult to eliminate or prevent exposure to all allergens that may trigger an asthma attack. To prevent these attacks, most asthmatics are treated with various pharmacological agents, many of which have side effects.

Pharmaceutical therapies in the absence of in vivo clinical data are unpredictable for the following reasons; (1) the protein may be inactivated before producing an effect, i.e. such as proteolytic degradation, immunological inactivation or due to an inherently short half-life of the protein; (2) the protein may not reach the target area because, i.e. the protein may not be able to cross the mucosa or the protein may be adsorbed by fluids, cells and tissues where the protein has no effect; and (3) other functional properties, known or unknown, may make the protein unsuitable for in vivo therapeutic use, i.e. such as adverse side effects prohibitive to the use of such treatment. See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

The specification does not adequately teach how to effectively prevent asthma attacks by administering anti-C5 antibodies. The specification does not teach how to extrapolate data obtained from various in vitro or in vivo observations with anti-C5 antibodies to the development of effective methods of preventing asthma attacks encompassed by the claimed invention.

Also, it is noted that experimental protocols usually are conducted under defined conditions wherein the antagonist and the stimulus / insult occur at the same or nearly the same time. Immunosuppression is much easier to achieve under such controlled conditions that experienced conditions such as asthma targeted by the claimed invention. With respect to in vivo studies, animal models validate concepts based on studies of human disease, such studies are limited to the "acute" as opposed to "chronic" nature of the disease. In animal models, the onset of inflammation is rapid with an aggressive destructive process, whereas in humans the disease progresses more slowly, often with natural periods of disease exacerbation and remission.

Here, while the skilled artisan may be able to ameliorate or dampen an asthma attack by the administration of anti-C5 antibodies, it would be unpredictable that the skilled artisan would prevent an asthma attack by the administration of anti-C5 antibodies.

There is insufficient guidance and direction as well as objective evidence to provide for prophylactically treating or preventing an asthma attack the claimed methods.

In view of the lack of predictability of the art to which the invention pertains the lack of established clinical protocols for effective methods to prevent an asthma attack with anti-C5 antibodies, undue experimentation would be required to practice the claimed methods of preventing asthma attacks with a reasonable expectation of success, absent a specific and detailed description in applicant's specification of how to effectively practice the claimed methods and absent working examples providing evidence which is reasonably predictive that the claimed methods are effective for preventing asthma attacks encompassed by the claimed methods and products.

Applicant is invited to amend the claims to avoid the recitation of "preventing" and prophylactically administering".

13. This is a rejection under 35 U.S.C. § 112, first paragraph, "written description" (and not New Matter).

Claims 52-58 are rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.

There is insufficient written description encompassing "compound", including "compounds selected from the group consisting of compounds which bind to one or more complement components, compounds which block the generation of one or more complement components, compounds which block the activity of one or more complement compounds and compounds which block the engagement of complement component receptors" because the relevant identifying characteristics such as structure of other physical and/or chemical characteristics of "compounds" are not set clearly defined either in the claims nor clearly set forth in the specification as filed, commensurate in scope with the claimed invention.

Similarly, there is insufficient written description encompassing "suitable compounds for combination therapy", including certain members of the "suitable compounds for combination therapy" recited in claims 20 and 51 (e.g., "steroids, β2 adreno receptor agonists, PDE inhibitors, CD23 antagonists, IL-13 antagonists, cytokine release inhibitors, histamine H1 receptor antagonists, anti-histamines and histamine release inhibitors") because the relevant identifying characteristics such as structure of other physical and/or chemical characteristics of "suitable compounds for combination therapy" are not set clearly defined either in the claims nor clearly set forth in the specification as filed, commensurate in scope with the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. For example in Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Thus, the specification fails to describe these DNA sequences.

The Court further elaborated that generic statements are not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. Finally, the Court indicated that while applicants are not required to disclose every species encompassed within a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, defined by nucleotide sequence, falling within the scope of the genus, See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Page 13, paragraph 2 of the instant specification provides for the limited disclosure of certain "compounds" as follows.

Any compound which bind to or otherwise block the generation and/or activity of any of the human complement components, such as, for example, antibodies specific to a human complement component are useful herein. Some 5 compounds include antibodies directed against complement components C-1, C-2, C-3, C-4, C-5, C-6, C-7, C-8, C-9, Factor D, Factor B, Factor P, MBL, MASP-1, AND MASP-2, thus preventing the generation of the anaphylatoxic activity associated with C5a and preventing the assembly of the membrane attack complex associated with C5b. Also useful in the present methods are naturally occurring or soluble forms of complement inhibitory compounds such as CR1, LEX-CR1, MCP, DAF, CD59, Factor H, cobra venom factor, FUT-175, y bind protein, complestatin, and K76 COOH.

Page 6, paragraph 2 of the instant specification provides for the limited disclosure of the suitable compounds for combination therapy as follows.

A combination therapy may also be used that includes a complement-inhibiting compound in combination with a regimen of known asthma therapy, such as, for example, steroids, anti-IgE antibodies, anti-IL-4 antibodies, anti-IL-5 antibodies, 132 receptor agonists, leukotriene inhibitors, 5 Lipoxygenase inhibitors, β2 adreno receptor agonists, PDE inhibitors, IL 5 antagonists, CD23 antagonists, IL 13 antagonists, cytokine release inhibitors, histamine H1 receptor antagonists, anti-histamines and histamine release inhibitors. Suitable compounds of each class listed above as well as other asthma treatments are listed in Asthma Therapeutic: New Treatment Options and Emerging Drug Discovery Targets, Barnes, April 2003, Lead Discovery, www.leaddiscovery.co, uk/target-discovery/abstracts/dossier-asth ma. Html.

Applicant is relying upon certain structural and biological activities and the disclosure of a limited representative number of species such as antibodies to known complement components and known complementary compounds to support an entire genus of "any compound" broadly encompassed by the claimed invention and described by the instant specification as-filed.

Similarly, the claims recited and the specification describes broad categories of "steroids, β2 adreno receptor agonists, PDE inhibitors, CD23 antagonists, IL-13 antagonists, cytokine release inhibitors, histamine H1 receptor antagonists, anti-histamines and histamine release inhibitors" as "suitable compounds for combination therapy".

Without sufficient description of "any compound" / "any suitable compound for combination therapy" other than identified in the specification as filed, the skilled artisan cannot practice the claimed invention. It means little to invent a method if one does not have possession of "any compound" / "any suitable compound for combination therapy" that would be essential to practice the claimed invention as broadly claimed. Without possession of the claimed genus of "compounds" / "suitable compounds for combination therapy" as broadly claimed and without possession of the correlation between the chemical structure and the function of the genus of "compounds" and the scope of the claimed "compounds" / "suitable compounds" are illusory and there is no meaningful possession of the scope of the claimed invention.

The instant claims do not provide functional characteristics coupled with a known or disclosed correlation between function and structure. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genera of "compounds" / "suitable compounds for combination therapy", and because the genus is variable, the reliance on the particular known complement inhibitors, including the elected anti-C5 antibodies set forth in specification as filed is insufficient to describe the genus of "compounds or general categories of "suitable compounds for combination therapy" broadly encompassed by the claimed invention.

The instant invention encompasses any "compound", other than the elected anti-C5 antibodies or other known "compounds" described in the specification as filed (e.g., see page 6, paragraph 2 of the specification);

yet the instant specification does not provide sufficient written description as to the structural features of the genus of "compounds" and the correlation between the chemical structure and the function of the genera of "compounds". The reliance on the disclosed limited examples of the limited species of the particular "anti-C5 antibodies" or those known "compounds described on page 6, paragraph 2 of the specification does not support the written description of any "compound", broadly encompassed by the claimed invention.

Also, there appears insufficient written description of those single compounds that have multiple targets consistent with the recitation of "compounds which bind / block the generation of / block the activity of one or more complement components" and "compounds which block the engagement of complement component receptors".

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112、1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species; then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus.

In the absence of structural characteristics that are shared by members of the genera of "compounds" or "suitable compounds for combination therapy",

one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. See University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997).

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. *For prior art purposes, "preventing asthma attacks and prophylactically administering" read on treatment of asthmatic patients as well as reading on dampening or ameliorating asthma attacks, under the broadest reasonable interpretation of the claims.*

17. Claims 1-18, 20-21 and 45-58 are rejected under 35 U.S.C. § 102(e) as being anticipated by Krause et al. (US 2004/0014782) (see entire document).

Krause et al. teach the use of C5a antagonists, including anti-C5 antibodies (e.g., see paragraphs [0207] and [0277]) in the treat respiratory diseases lung disorders, including ARDS and asthma (e.g., see paragraphs [0039], [0204] [0227, [0274]), including inhaled compositions, nebulizers or other devices for the treatment of asthma (e.g., see paragraphs [0273]—[0275], [0279]-[0281], [0288]-[[0303]) as well as combinations for the treatment of lung disorders (e.g., see paragraphs [0200], [0226]-[0235]) and dosages consistent with the broad range (e.g., see paragraphs [0263]-[0300]) (see entire document).

Although the reference does not disclose that all of the properties of functional or binding characteristics of antagonistic anti-C5 antibodies recited in the claims per se (e.g., reducing airway obstruction, reducing bronchial spasms, increasing airflow, inhibits the conversion of complement component C5 into C5a and C5b, etc.),

it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). "{i}t is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable". In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

On this record, it is reasonable to conclude that the same patient is being administered the same active agent by the same mode of administration in the same amount in both the instant claims and the prior art reference. The fact that applicant may have discovered yet another beneficial effect from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method.

Note that eculizumab or pexelizumab described in paragraphs [0207] is the same as 5G1.1., h5G1.1.

18. Claims 1-18, 20-21 and 45-58 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Krause et al. (US 2004/0014782) (1449; #AE) in view of Evans et al. (U.S. Patent No. 6,355,245), Lobb et al. (U.S. Patent No. 5,871,734) (1449; #AA) and the known regimens of asthma therapy, as acknowledged on page 6, paragraph 2 of the specification.

Krause et al. teach the use of C5a antagonists, including anti-C5 antibodies (e.g., see paragraphs [0207] and [0277]) in the treat respiratory diseases lung disorders, including ARDS and asthma (e.g., see paragraphs [0039], [0204] [0227, [0274]), including compositions for the treatment of asthma (e.g., see paragraphs [0273]—[0275], [0279]-[0281], [0288]-[[0303]) and instructions (e.g., see claim 29, paragraphs 263, [0273], [0278], [0297]) as well as combinations for the treatment of lung disorders (e.g., see paragraphs [0200], [0226]-[0235]) and dosages consistent with the broad range recited in claim 31 (e.g., see paragraphs [0263]-[0300]) (see entire document).

Although the reference does not disclose that all of the properties of functional or binding characteristics of antagonistic anti-C5 antibodies recited in the claims per se (e.g., reducing airway obstruction, reducing bronchial spasms, increasing airflow, inhibits the conversion of complement component C5 into C5a and C5b, etc.),

it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). "{i}t is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable". In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

Furthermore, the functional or binding characteristics of antagonistic anti-C5 antibodies recited in the claims (e.g., reducing airway obstruction, reducing bronchial spasms, increasing airflow, inhibits the conversion of complement component C5 into C5a and C5b, etc.) in the treatment of asthma or other pulmonary inflammatory conditions would have been obvious therapeutic endpoints in view of the teachings of the therapeutic utilities of the antagonistic anti-C5 antibodies taught by Krause et al., as these therapeutic endpoints would have been obvious therapeutic endpoints in the amelioration or treatment of said inflammatory pulmonary conditions.

In addition, Evans et al. provides for a more complete teachings of making and using 5G1.1 anti-C5 antibody in inhibiting inflammation, including the binding and functional characteristics recited in claims 12-16) (see entire document).

Note that eculizumab or pexelizumab described in paragraphs [0207] is the same as 5G1.1., h5G1.1.

In addition, page 6, paragraph 2 of the instant specification acknowledges the known reagents employed in asthma regimens.

Given the teachings of combination therapy by Krause et al., it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ antagonistic anti-C5 antibodies in combination with the known regiments either taught by Krause et al. or as acknowledged by page 6, paragraph 2 of the instant specification as equivalents or obvious substitutions regularly practiced by the ordinary artisan at the time the invention was made.

In addition to the teachings above, Lobb et al. teach that aqueous antibody solutions can be delivered to airways using a nebulizer (e.g., see column 6, lines 36-41 and column 12, lines 37-52) as well as the use of antibodies for the treatment of asthma (see entire document, including Summary of the Invention). Note, too, that Lobb et al. also teach the well known applicability of combination therapy, including combination having a therapeutic effect on airway responsiveness (e.g., see column 8, paragraphs 4-5).

On this record, it is reasonable to conclude that the same patients are being administered the same active agent by the same mode of administration in the same amount in both the instant claims and the prior art reference

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to employ combination therapy with anti-C5a antibodies in the treatment of certain respiratory / lung disorders / diseases such as asthma One would have been motivated with a reasonable expectation of success to administer the antibodies directly to the respiratory mucosa, which is often the first line of encounter of an immune system with pathogenic organisms and by the teachings of the prior art as a known and effective means to target the respiratory system in the treatment of certain disorders/diseases.

"The test of obviousness is not express suggestion of the claimed invention in any or all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them." See In re Rosselet, 146 USPQ 183, 186 (CCPA 1965).

"There is no requirement (under 35 USC 103(a)) that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art." Motorola, Inc. v. Interdigital Tech. Corp., 43 USPQ2d 1481, 1489 (Fed. Cir. 1997).

An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. See KSR Int'l Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.").

Given that the prior art goal was to inhibit complement activation in order to treat pulmonary diseases/conditions,
incorporating known inhibitors such as anti-C5 antibodies into therapeutic regiments to treat inflammatory lung / pulmonary conditions such as asthma would have been routine to the ordinary artisan at the time the invention was made and therefore obvious in designing therapeutic regimens to treat such inflammatory pulmonary diseases / conditions.

From the teachings of the references, a person of ordinary skill in the art would have a reasonable expectation of success at the time the invention was made. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 1-18, 20-21 and 45-58 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 31-45 of copending USSN 11/127,438.

The instant and copending claims are drawn to the same or nearly the same methods of treating pulmonary conditions such as asthma with the same anti-C5 antibodies. Combination therapy in the treatment of various conditions, including pulmonary conditions / asthma were well known in the prior art at the time the invention was made.

The instant and copending claims either anticipate or render obvious one another.

20. No claim is allowed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phillip Gambel/
Primary Examiner
Technology Center 1600
Art Unit 1644
October 21, 2010